HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
4298 Elysian Fields Avenue
New Orleans, LA 70122-3896
Telephone (504) 589-7166
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August 13, 1997

WARNING LETTER NO. 97-NOL-57

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Eric O. Nguyen
President/Owner
C & J Seafood and Crab Co., Inc.
116 North Hollywood Road
Houma, Louisiana 70364

Dear Mr. Nguyen:

During an inspection of your processing facility by the U.S. Food and Drug Administration on August 4-6, 1997, our investigator documented numerous insanitary conditions. These conditions cause your product, picked crabmeat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act.

The objectionable insanitary conditions observed include:

1. inadequate sanitation of the cart used to transport both perforated crates of cooked product and residue encrusted trash cans filled with crab waste;

2. hundreds of live flies present inside and outside the processing plant, including on cooked product, on crab boxes and on discarded dead product;

3. hundreds of live ants present on crate containing inprocess product and on cookroom wall baseboard during processing operations;

4. no detectable chlorine present in the sanitizing solution;

5. residues from previous operations remain on processing equipment and food contact surfaces;

6. inadequate sanitation of employees' gloves, hands and aprons which routinely contact cooked product after contact with insanitary surfaces, such as product from the floor and floor drains, unsanitized equipment and residue encrusted trash cans;

7. a perforated crate containing backed crabs rested directly on a residue encrusted trash can containing crab waste;

8. numerous other improper employee practices during processing operations.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 10 days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within 10 days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the Agency staff, you may contact Mrs. Hardin at telephone number (504)589-7166.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483
21 CFR 110 (4-1-97 Edition)
21 CFR 123 (4-1-97 Edition)

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